भारतीय मानक

Indian Standard

IS 17714 : 2023

इन-विट्रो डायग्नोस्टिक (आईवीडी) उपकरण — स्वचालित एलिसा प्रोसेसर

In-Vitro Diagnostic (IVD) Device — Automated ELISA Processor

ICS 11.100.10

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भारतीय मानक ब्यूरो
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November 2023 **Price Group 5**

In-vitro Diagnostic Medical Devices and Biological Evaluation of Medical Devices Sectional Committee, MHD 19

FOREWORD

This standard was adopted by the Bureau of Indian Standards, after the draft finalized by the *In-vitro* Diagnostic Medical Devices and Biological Evaluation of Medical Devices Sectional Committee had been approved by Medical Equipment and Hospital Planning Division Council.

This standard specifies the general requirements and standard test procedures for Performance Testing of *In-Vitro* Diagnostic (IVD) devices – ELISA processor. These are used to detect biological, chemical, or physical events of samples in microtiter plates. They are widely used in research, drug discovery, bioassay validation, quality control and manufacturing processes in the pharmaceutical and biotechnological industry.

The composition of the Committee responsible for formulation of the standard is given in Annex A.

For the purpose of deciding whether a particular requirement of this standard is complied with the final value, observed, or calculated, expressing the result of a test or analysis shall be rounded off in accordance with IS 2 : 2022 'Rules for rounding off numerical values (*second revision*)'. The number of significant places retained in the rounded off value shall be the same as that of the specified value in this standard.

Indian Standard

IN-VITRO DIAGNOSTIC (IVD) DEVICE — AUTOMATED ELISA PROCESSOR

1 SCOPE

This standard specifies the general requirements and the performance test procedure for the *in-vitro* diagnostic (IVD) instrument — Automated ELISA plate processor.

2 REFERENCES

The standards given below contain provisions which, through reference in this text, constitute provisions of this standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this standard are encouraged to investigate the possibility of applying the most recent edition of these standards.

IS No.	*Title*
IS/ISO 13485 : 2016	Medical devices — Quality management systems — Requirements for regulatory purposes (*first revision*)
IS/ISO 14971 : 2019	Medical devices — Application of risk management to medical devices (*first revision*)
IS 17724	Safety requirements for electrical equipment for measurement, control, and laboratory use:
(Part 1) : 2023	General requirements
(Part 4) : 2023	Particular requirements for *In-vitro* diagnostic IVD medical equipment
IS 17784	Electrical equipment for measurement, control and laboratory use — EMC requirements
(Part 1) : 2023	General requirements
(Part 2) : 2023	Particular requirements for *In-vitro* diagnostic (IVD) medical equipment

3 TERMS AND DEFINITION

3.1 ELISA Plate Processor

Automated ELISA plate processor is a device used to automate and maximize the efficiency of ELISA testing in the microplates, with automatic sample handling, incubation, washing and data reading section.

4 PRINCIPLE

4.1 The Automated ELISA processor constitutes the following sections:

a) Sample and reagent handling section;
b) Incubation, mixing and shaking section;
c) Washing section; and
d) Data reading section.

5 REQUIREMENTS

5.1 General Requirements

The ELISA Processor shall comply with the requirements as specified in IS 17724 (Part 1) and IS 17724 (Part 4).

5.2 Electromagnetic Compatibility Requirements

The ELISA Processor shall comply with the requirements as specified in IS 17784 (Part 1) and IS 17784 (Part 2).

6 PERFORMANCE MEASUREMENT AND QUALIFICATION PROCEDURE

6.1 Sample Volume

The sample pipette assembly shall be able to aspirate and dispense with high accuracy and precision in each and every well of the microplates.

6.1.1 *Test Procedure for Evaluating Accuracy and Precision*

6.1.1.1 The test is performed for the sample volumes 10 µL, 25 µL, 50 µL, 75 µL and 100 µL. 100 µL of deionized water is added in all the wells. Then, the known dye solution is dispensed. The sample volumes are dispensed manually for reference readings. The reading of the analyser is recorded. The mean, standard deviation and percent coefficient of variation are calculated. The bias between reference reading and the recorded reading is then calculated. The accuracy of sample volume shall be ± 5 percent. The precision of sample volume shall be ± 0.5 µL or 3 percent, whichever is higher.

6.2 Reagent Volume

The processor shall be able to support different reagent volume and the pipetting shall be accurate and precise in each and every well of the microplates.

6.2.1 *Test Procedure for Evaluating Accuracy and Precision*

6.1.1.2 The test is performed for the sample volumes 10 µL, 25 µL, 50 µL, 75 µL and 100 µL. 100 µL of deionized water is added in all the wells. Then, the known dye solution is dispensed. The sample volumes are dispensed manually for reference readings. The reading of the analyser is recorded. The mean, standard deviation and percent coefficient of variation are calculated. The bias between reference reading and the recorded reading is then calculated. The accuracy of sample volume shall be ± 5 percent. The precision of sample volume shall be ± 0.5 µL or 3 percent, whichever is higher.

6.3 Incubation, Mixing and Shaking Section

6.3.1 Incubation at a specific temperature and duration is required for ensuring the optimum degree of bonding reaction in the microplates. The processor shall have programmable incubation time and temperature.

6.3.2 Mixing and shaking is essential in order to achieve the optimum bonding or reaction. The processor shall have programmable shaking speed and duration.

6.4 Washing Section

6.4.1 *Residual Volume* Test

6.4.1.1 The plate wash is performed using deionized water or wash buffer solution. The residual volume is measured. The mean residual volume shall be less than 5 µL.

6.4.2 The processor shall have programmable wash cycles and programmable soak time.

6.5 Data Reading Section

6.5.1 *Accuracy of Photometric Measurement*

6.5.1.1 The neutral density filter strips/plates of various optical densities are inserted into the processor. The strips/plates are read at all wavelengths available in the instrument. The obtained results are compared with the reference optical density value of the strips/plates. The photometric accuracy shall be ± 5 percent for all wavelengths for all strips/plates.

6.5.2 *Precision of Photometric Measurement*

6.5.2.1 The neutral density filter strips/plates of various optical densities are inserted into the processor. The strips/plates are read 20 times at all wavelengths available in the instrument. The obtained results are compared with the reference optical density value of the strips/plates. The mean, standard deviation and percent coefficient of variation for each well are calculated. The photometric precision accuracy shall be 3 percent.

6.5.3 *Linearity of Photometric Measurement*

6.5.3.1 The neutral density filter strips/plates of various optical densities are inserted into the processor. The strips/plates are read at all wavelengths available in the instrument. The obtained results are compared with the reference optical density value of the strips/plates. The values are also measured using spectrophotometer. The absorbance value obtained using the processor is plotted on y-axis and that obtained using spectrophotometer is plotted on x-axis. The linear regression analysis is then performed. The slope, intercept and coefficient of correlation are estimated. The photometric linearity shall be $0.95 < r^2 < 1$, slope shall be 1 ± 0.05 and the intercept shall tend to 0.

6.5.4 *Stability of Photometric Measurement*

6.5.4.1 The neutral density filter strips/plates of various optical densities are inserted into the processor. The strips/plates are read at all wavelengths available in the instrument. Subsequent readings are taken after duration of 10 minutes, 20 minutes and 30 minutes. The difference between the obtained maximum absorbance value and minimum absorbance value is calculated. The photometric stability shall be less than 0.01 absorbance.

7 RISK MANAGEMENT AND QUALITY CONTROL

7.1 The processor shall comply with IS/ISO 14971 with the risk management process for the device.

7.2 The manufacturer of the processor shall comply with the quality management system standard IS/ISO 13485.

8 OPERATING MANUAL

The processor shall be accompanied with the operating manual with the following information:

a) Instructions for installation;
b) Manual for operation of the processor; and

c) Routine maintenance and service procedure.

9 MARKING, LABELLING AND PACKAGING

9.1 The processor shall be legibly and indelibly marked at suitable place with the following details:

a) Product name along with the phrase "**for *in-vitro* diagnostic use only**";
b) Name of the manufacturer and address;
c) Country of manufacture;
d) Serial number; and
e) Warning labels.

9.2 The processor shall be packed securely with suitable material, to ensure that the risk of damage is minimized during the transportation.

9.3 Proper decontamination procedure shall be followed before packing the processor.

9.4 BIS Certification Marking

The product(s) conforming to the requirements of this standard may be certified as per the conformity assessment schemes under the provisions of the *Bureau of Indian Standards Act*, 2016 and the Rules and Regulations framed thereunder, and the product(s) may be marked with the Standard Mark.

ANNEX A

(*Foreword*)

COMMITTEE COMPOSITION

In-vitro Diagnostic Medical Devices and Biological Evaluation of Medical Devices Sectional Committee, MHD 19

Organization	*Representative(s)*
In Personal Capacity (*E117 first floor Greater Kailash 2, New Delhi, 110048*)	Dr Reba Chabbra **(*Chairperson*)**
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